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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,434	02/28/2001	Wilfried Fischer	2727-130	5919

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EXAMINER
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GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 11/21/2001

6

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/700,434

Applicant(s)

FISCHER, WILFRIED

Examiner

Sharmila S. Gollamudi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☒ Claim(s) 2 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Claims 1-16 are included in the prosecution of this application.

Preliminary Amendments are acknowledged.

#### ***Information Disclosure Statement***

The references cited in the Search Report have been considered, but will not be listed on any patent resulting from this application because they were not provided on a separate list in compliance with 37 CFR 1.98(a)(1). In order to have the references printed on such resulting patent, a separate listing, preferably on a PTO-1449 form, must be filed within the set period for reply to this Office action.

#### ***Claim Objections***

Examiner suggests that "further comprising" is inserted into line 3 of claim 2 so that the claim reads "further comprising adhesive layer (2)" since adhesive layer (2) is not in claim 1.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

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Claim 1 is indefinite because it is not known which layer the water-soluble material is located. Is it a layer by itself or is it in the cover layer?

Claim 13 is indefinite since it is not understood if the woven or non-woven fabric is in the adhesive layer or on top of the adhesive layer. The recitation "the adhesive layer contain a net, woven fabric, or non-woven fabric" implies that it is in the layer but the recitation that the fiber thickness be thinner than the adhesive layer implies that it is separate from the adhesive layer.

The term "re-detachable" in claim 14 is a relative term which renders the claim indefinite. The term "re-detachable" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The instant term is not defined in the dictionary.

Further, in claims 1-3, 5, and 7-14, are indefinite since claims should stand on their own and not refer to the specification or drawings. Examiner suggests using the name of the layer rather than using numerical numbers corresponding to drawings to refer to layers.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The

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Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 8 and 9 recite the broad recitations 10-300 microns in claim 8 and 1-300 microns in claim 9, and the claim also recites 30-100 microns in claim 8 and 3-100 microns in claim 9 which are the narrower statements of the range/limitation. In claim 11, the broad limitation of "water-vapor-impermeable materials" followed by the narrow limitation of "especially polyester, preferably polyterephthalic acid ester..." is indefinite. In claim 13, the broad limitation of the "the thread or fiber thickness" followed by the narrow limitation of "preferably being less than the thickness of the adhesive layer is indefinite. In claim 14, the broad limitation of "the protective layer is re-detachable" followed by the narrow limitation of "especially a siliconised plastics..." is indefinite.

Claim 16 provides for the use of the transdermal system, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 16 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper

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definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-4, 6-12, 14, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/24172.**

WO 95/24172 discloses transdermal delivery system, which has a backing (cover layer), a pressure-sensitive adhesive drug composite layer, and a release liner (protective layer) (Note Fig. 1). The reference teaches a gelled drug layer containing hydroxycellulose between two active-free adhesive layers (pg. 19, line 1 and Fig. 1). The art reads in instantly claimed thickness (pg. 16, lines 20-23). The backing and release liner are made of silicon polyester (pg. 15, line 5 and Ex. 2). WO 95/24172 teaches the use of the device for treating nicotine withdrawal (pg. 2, lines 5-23).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/24172 as cited above.**

As set forth above, WO 95/24172 teaches a transdermal delivery system and discloses materials that may be used in the adhesive layer such as polyurethane (pg. 16, lines 23-37 and claim 9).

WO 95/24172 does not teach a porous polymer layer or a specific fabric to be used in the adhesive layer.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a fabric in the adhesive layer since the prior art suggests polyurethane as one of the materials to be used. One would be motivated to do so since the selection of the adhesive affects the release rate of the drug, the material chosen is dependent on what type of drug is administered and how fast the drug needs to be released.

**Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/24172 in view of Sweet et al (4882377).**

As set forth above, WO 95/24172 discloses a transdermal drug delivery system. The reference suggests the use of silicon elastomers.

WO 95/24172 does not specifically teach the use of silicon elastomers in the backing and release layer.

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Sweet et al disclose a pressure-adherent silicon elastomer composition in a transdermal drug delivery patch (col. 1, lines 5-26). Sweet et al teach the advantages of using a silicon elastomer such as its ability to maintain tack and cohesiveness even in moist conditions, it causes little irritation to the skin, and is easily molded without heat (col. 2, lines 33-68).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use silicon elastomers for the release liner and backing layer. One would have been motivated to do so since sweet et al teach the advantages of using the instant material in transdermal delivery systems such as WO 95/24172.

**Claim 5 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/24172 cited above in view of WO 89/07959.**

As set forth above, WO 95/24172 discloses a transdermal delivery system and nicotine as the active agent. The reference discloses that nitroglycerin as a transdermally administered agent (pg. 2, lines 13-15).

WO 95/24172 does not teach perforations in drug composite layer for a constant rate of release of active agent. Further, the reference discloses nitroglycerin as the active ingredient or the system to be used to treat Angina pectoris.

WO 89/07959 teaches an occlusive body patch for transdermal administration of active agents. The reference teaches the use of a microporous polymer in the active layer (Note Abstract and pg. 7, lines 11-25). Further, the reference discloses that nitroglycerine may be substituted for nicotine (pg. 11, line 11).



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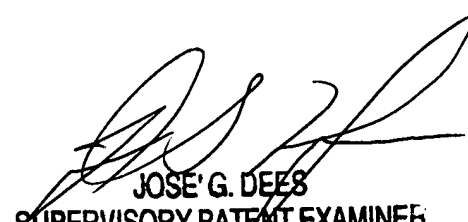
It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of both references since both teach transdermal patches. One would be motivated to have a microporous polymer in the active layer to control the rate of release. Further, one would be motivated to use nitroglycerin since the active agent is dependent on the type of disorder treated, thus one would use nitroglycerine, transdermally administered agent, to treat Angina pectoris in a the transdermal drug delivery system such as WO 95/24172.

Any inquiry concerning this communication from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can be normally reached M-F from 7:30 am to 4:15pm.

If attempts to reach the examiner by the telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached at (703) 308-4628. The fax number for this organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, whose telephone number is (703) 308-1235.

SSG

  
JOSE G. DEES  
SUPERVISORY PATENT EXAMINER  
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